

B 1  
connected to said toroidal shaped bladder, whereby said coolant from said source flowing through said inlet and outlet coolant conducting elements cools said bladder, further whereby when said first end of said endotracheal tube is inserted into said patient's trachea, said coolant flowing in said bladder lowers the temperature of [the] said tissues and blood vessels of said patient's oral cavity in contact with said bladder, said tissues and blood vessels further acting as heat conducting paths from said brain to said bladder whereby the temperature of said brain is lowered.

Sub CTS  
B 2  
12. (Once Amended) A method of inducing hypothermia in a patient's brain comprising the step of:  
a) cooling said brain by lowering the temperature of the blood flowing in blood vessels located in [the rear of] said patient's oral cavity.

#### REMARKS

The claims remaining in the application are Claims 7,8,9, 12 and 13. Claims 10, 11 and 14 have been canceled.

2,3. Claims 7,8,9,12 and 13 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 has been amended in paragraph (c) to include " a source of liquid or gaseous coolant". Support is provided in the specification, Page 3, lines 8-10, "The coolant flowing...may be any of the well known liquid or gaseous refrigerants...". Paragraph (a) of Claim 7 has been amended to specify first and second ends of the endotracheal tube. A finite length endrotracheal tube is shown

//

in Fig. 3, inherently having first and second ends. Similarly, "tissues and blood vessels" are inherently part of a patient's oral cavity. The bladder of applicant's invention contacts the tissues and blood vessels associated with the patient's oral cavity is supported in the specification, page 4, lines 27-28, page 5, line 1, " ...cooling the back of the oral cavity 35, and attendantly the blood vessels located in the oral cavity 35." The phrase "the rear of" has been deleted from Claim 12, line 4, as being extraneous.

4,5. Claim 12 stands rejected under 35 U.S.C. 102(b) as being anticipated by Cohen. The Examiner makes the following statement in the Office Action: "The Examiner asserts that the use of the Cohen device in the forementioned embodiment will lower the temperature of the blood flowing through vessels located in the rear of the patient's oral cavity." Applicant traverses this assertion which is made without any supporting evidence in the form of prior art patent references or supporting scientific documentation. Cohen discloses a pad which externally applies a coolant to the surface of a patient's forehead, skull and neck. (Cohen, Fig. 5). There is no disclosure in Cohen that his structure will cause quick cooling of the blood vessels of the patient's oral cavity and attendantly the brain, which is central to Applicant's claimed invention. Applicant's invention is directed to inducing rapid hypothermia in the brain to reduce the chance of tissue damage when the brain is deprived of oxygen. In refutation of the Examiner's assertion, Applicant submits as Appendix A, the article "Selective brain cooling after cardiac arrest" from the medical periodical "Critical Care Medicine", Vol.24, No. 6, pp.911-913, and respectfully direct the Examiner's

B

attention in particular to the hi-lited paragraphs. These experiments show the inefficiency in brain temperature reduction by externally applied cooling techniques. Based on this experimental data, Applicant maintains that the Cohen externally applied surface device will fall woefully short of providing rapid reduction of internal organ temperature, including oral cavity as well as brain temperature, and is clearly distinguishable from, and does not anticipate, Applicant's internally applied cooling method. Applicant respectfully requests that the 35 U.S.C. 102(b) rejection of Claim 12 be withdrawn.

8,9. Claims 7-8 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baran et al in view of Durkan. Baran et al disclose " A multiple surgical cuff for introduction into a body passage....comprising a tubular base member encircled by proximal, distal and middle double cuff members." (Baran et al, Abstract, line 1). Among its proposed uses is as an endotracheal tube, and this application is disclosed in detail in their specification. It will be noted that the disclosed invention is a linearly extending tube for total insertion into a body passage, such as the trachea, and that the surrounding cuffs, which are now positioned inside the body passage, are then to be expanded to make contact with the interior walls of the trachea as shown in Baran et al Fig. 2. The cuffs A, B, C are there seen in contact with the walls of the trachea G. The two outboard cuffs when inflated seal off the portion of the body passage wherein they are located, "...the distal and proximal cuffs when they are inflated to sealing contact with the body passage." (Baran et al, Column 2, lines 47-48), and again,

"...when the distal and proximal cuffs are in sealing contact with the body passage..."(Baran et al, Column 2, lines 49-50). Hence, the distal and proximal cuffs come into play to seal off a portion of the body passage into which the entire device has been inserted. It is important to note that middle cuff A is not only a double cuff, (distinguishable from Applicant's single wall bladder) but that its surrounding external cuff D has multiple openings M. "...local anesthetic is sprayed through multiple openings M..." (Baran et al, Column 5, lines 9-10). These multiple openings also are employed as described as follows; "...different pharmaceutical agents....may be applied to the bleeding segment via the anesthetic canal S, the space between the internal cuff E and the external multiperforated cuff D and the multiperforations M when the internal cuff E is expanded. [Paragraph] Further, the bleeding segment may be irrigated by cool saline solution and debris removed via the suction opening X." (Column 7, lines 57-66). Thus any cooling performed by the Baran et al is by a solution in direct washing contact with the tissues of the walls of the body passage in the sealed off space, with the solution being forced out under pressure through the perforations M and then sucked out by suction tube W. There is no such structure in Applicant's disclosed and claimed invention; his refrigerant circulates through Applicant's non-perforated bladder, and heat flow occurs through the walls of the bladder from the patient's tissue and blood vessels in physical contact with the cold integral surface of the bladder. There is no structure in Baran et al that duplicates or suggests the toroidal single walled bladder carrying a refrigerant set forth in Applicant's disclosure.

Durkan discloses a cuffed endotracheal tube. "The cuff 70 is a toroidal shaped inflatable device that fits into the patient's trachea and surrounds the tracheal tube 16a through which oxygen is supplied to the lungs. When the cuff 70 is inflated it forms a seal around the tracheal tube..." ( Durkan, Column 6, lines 9-14). Applicant traverses the Examiner's comment that, "It would have been obvious to one skilled in the art to shape the cuff of Baran in the form of a toroid..." Baran et al's cuffs are already substantially in the form of toroids surrounding their tubular member, (Baran et al, Figs. 1,2 ), and serve to seal off the body passage wherein they are located. (See discussion supra of Baran et al re sealing). Durkan in the above quoted lines from his specification uses an inflatable toroid also to seal off the trachea. Applicant maintains that one skilled in the art would find no motivation to combine Baran et al and Durkan, because Baran et al already provide not one sealing member in the form of toroids but two of them, i.e. cuffs B and C. Applicant also asserts that even if one were to combine the teachings of Baran et al and Durkan, the resultant device would not replicate the inventive structure of Applicant's disclosure because Baran et al's fluid is in direct contact with the tissue of the body passage, and Durkan discloses inflating his toroid with air for sealing purposes. In view of the preceding, Applicant respectfully requests that the 35 U.S.C. 103(a) rejections of Claims 7, 8, 13 be withdrawn.

10. Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Baran et al and Durkan as applied to Claims 7-8 above, and further in view of Klatz et al. Applicant has addressed the combining of the Baran et al and Durkan references

supra, and respectfully relying on the inapplicability of these references in a 35 U.S.C. 103(a) rejection stated therein also states that combining them with Klatz et al will not support the above cited rejection of Claim 9, and Applicant requests that the rejection of Claim 9 be withdrawn.

Applicant has carefully amended the claims, and has also carefully discussed the references cited, and Applicant believes the claims are now in condition for allowance. Applicant respectfully requests that the claims remaining in the application be allowed, and the application be passed to issue.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Daniel Robbins".

Daniel Robbins  
Reg. No. 30,583

Telephone: 619-546-0842  
Fax: 619-546-9257